K030304
1 of 2

NOV 1 2 2003

510(k) Summary of Safety and Effectiveness

Date: October 9, 2003

Submitter: GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: Melissa Robinson
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
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Milwaukee, WI 53223 USA
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Device: Trade Name: Dash 3000/4000 Patient Monitor

Common/Usual Name: Physiological Patient Monitor

Classification Names:

21 CFR 868.1400	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase	CCK
21 CFR 868.2375	Breathing Frequency Monitor	FLS
21 CFR 870.1025	Detector and Alarm, Arrhythmia	DSI
21 CFR 870.1100	Monitor, Blood Pressure, Indwelling	CAA
21 CFR 870.1130	Noninvasive Blood Pressure Measurement System	BXD
21 CFR 870.1100	Blood Pressure Alarm	DSJ
21 CFR 870.1425	Programmable Diagnostic Computer	DQK
21 CFR 870.2340	Electrocardiograph	FYW
21 CFR 870.1435	Monitor, Cardiac Output, Thermal (Balloon Type Catheter)	KFN
21 CFR 880.2910	Monitor, Temperature (with probe)	BWX
21 CFR 870.2300	Monitor, Cardiac (Incl. Cardiotachometer & rate alarm)	DRT
21 CFR 870.2700	Oximeter, Pulse	DQA
21 CFR 870.1025	Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)	MHX
21 CFR 870.2770	Plethysmograph, Impedance	DSB

Predicate Device: K030431 Dash 3000/4000 Patient Monitor

Device Description: The Dash 3000/4000 Patient Monitor is a device that is designed to be used to monitor, display, and print a patient's basic physiological parameters including: electrocardiography (ECG), invasive blood pressure, non-invasive blood pressure, oxygen saturation, temperature, impedance respiration, end-tidal carbon dioxide, oxygen, nitrous oxide and anesthetic agents. Other features include arrhythmia, cardiac output, cardiac and pulmonary calculations, dose calculations, PA wedge, ST analysis, and interpretive 12 lead ECG analysis (12SL). Additionally, the network interface allows for the display and transfer of network available patient data.

Intended Use: The Dash 3000/4000 Patient Monitor is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use of the system is to monitor physiologic parameter data on adult, pediatric and neonatal patients. The Dash is designed as a bedside, portable, and transport monitor that can operate in all professional medical facilities and medical transport modes including but not limited to: emergency department, operating room, post anesthesia recovery, critical care, surgical intensive care, respiratory intensive care, coronary care, medical intensive care, pediatric intensive care, or neonatal intensive care areas located in hospitals, outpatient clinics, freestanding

surgical centers, and other alternate care facilities, intra-hospital patient transport, inter-hospital patient transport via ground vehicles (i.e., ambulance, etc.) and fixed and rotary winged aircraft, and pre-hospital emergency response.

Physiologic data includes but is not restricted to: electrocardiogram, invasive blood pressure, noninvasive blood pressure, pulse, temperature, cardiac output, respiration, pulse oximetry, carbon dioxide, oxygen, and anesthetic agents as summarized in the operator's manual.

The Dash 3000/4000 Patient Monitor is also intended to provide physiologic data over the Unity network to clinical information systems and allow the user to access hospital data at the point-of-care.

This information can be displayed, trended, stored, and printed.

The Dash 3000/4000 Patient Monitor was developed to interface with non-proprietary third party peripheral devices that support serial data outputs.

Technology: The Dash 3000/4000 Patient Monitor employs the same functional technology as the predicate devices.

Test Summary: The Dash 3000/4000 Patient Monitor complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the system:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion: The results of these measurements demonstrated that the Dash 3000/4000 Patient Monitor is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2003

GE Medical Systems Information Technologies
c/o Ms. Melissa Robinson
Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K033304
Trade Name: Dash 3000/4000 Patient
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: October 9, 2003
Received: October 14, 2003

Dear Ms. Robinson:

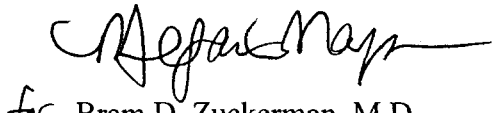
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033304

Device Name: Dash 3000/4000 Patient Monitor

Indications For Use:

The Dash 3000/4000 Patient Monitor is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use of the system is to monitor physiologic parameter data on adult, pediatric and neonatal patients. The Dash is designed as a bedside, portable, and transport monitor that can operate in all professional medical facilities and medical transport modes including but not limited to: emergency department, operating room, post anesthesia recovery, critical care, surgical intensive care, respiratory intensive care, coronary care, medical intensive care, pediatric intensive care, or neonatal intensive care areas located in hospitals, outpatient clinics, freestanding surgical centers, and other alternate care facilities, intra-hospital patient transport, inter-hospital patient transport via ground vehicles (i.e., ambulance, etc.) and fixed and rotary winged aircraft, and pre-hospital emergency response.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033304

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)